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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,104	02/04/2000	Paul M Scopton	1001.1375101	8323

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Robert E Atkinson  
Crompton Seager & Tufte LLC  
331 Second Avenue South  
Suite 895  
Minneapolis, MN 55401-2246

EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/498,104

Applicant(s)

SCOPTON, PAUL M

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5, 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (USPN 5531700).

Moore et al. discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figure 4, and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein. (Figure 4, and entire reference).

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figure 4, and entire reference).

2. Claims 1-5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Salmon et al. (5314408).

Salmon et al. discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figures 9 & 10, and entire reference).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft,

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Wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein, and wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figures 9 & 10, and entire reference).

3. Claims 1-5, 7, 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Crittenden et al. (4988356). Crittenden et al. discloses et al. a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein, and further comprising a balloon and an inflatable lumen within the shaft.

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion

of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein.

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port, and where the tubular member has as length of approximately 5-30 cm and a heat shrink tube. (Figures 1, 7, 9, 11, 12 and entire reference).

4. Claims 1-5, 7-9, and 10-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Willard et al. (5219335).

Willard et al. discloses a biliary catheter comprising an elongated shaft having a proximal end, a distal end, and an injection lumen extending therethrough, a guidewire lumen extending through a distal portion of the shaft between a proximal guidewire port and a distal guidewire port, the guidewire lumen being in fluid communication with the injection lumen of the shaft, the proximal guidewire port disposed proximal of the distal end of the shaft and distal of the proximal end of the shaft, the distal guidewire port disposed at the distal end of the shaft; and a tubular member connected to the shaft, the tubular member extending proximally from the proximal guidewire port to a proximal end disposed distal of the proximal end of the shaft, the tubular member defining a guidewire lumen extension adapted to permit the guidewire to be retracted from guidewire lumen and re-inserted therein. (Figures 1, 10, 13, 14, 17 and entire reference).

Wherein the tubular element is 5 to 30cm. (Figure 17, Column 12).

Wherein the tubular member has a distal end disposed distal of the proximal guidewire port, and where the member is disposed about the shaft, and wherein the distal end of the tubular is fluidly sealed about the shaft, and wherein a proximal portion of the guidewire lumen extension is sized to restrict flow about the guidewire disposed therein. (Figures 1, 10, 13, 14, 17 and entire reference).

Wherein the guidewire lumen extension is axially aligned with the guidewire port, and wherein the shaft of the catheter is radially shifted at the proximal guidewire port such that the guidewire may remain substantially straight through the proximal guidewire port. (Figures 1, 10, 13, 14, 17 and entire reference).

Further comprising a balloon catheter with an inflatable balloon and an inflatable lumen.

### ***Response to Arguments***

5. Applicant's arguments filed on 10/09/2002 have been fully considered but they are not persuasive.

In the prior art reference, Moore et al. the guidewire lumen is axially aligned with the guidewire lumen at the proximal end of the guidewire lumen extension. In Moore et al. also discloses passing the guidewire through the guidewire port and maintaining the guidewire to be "substantially straight," there is a slight curve but in the examiner interpretation of "substantially straight" the reference reads on the claim.

**Conclusion**

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.



Matthew DeSanto  
Art Unit 3763  
December 19, 2002

17  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

12/27/02